

AUG 29 2000

K002464

## 510(k) Summary of Safety and Effectiveness

Trade Name: Smith & Nephew Off-Centered PORP  
Common Name: Partial Ossicular Replacement Prosthesis  
Classification Name: Partial Ossicular Replacement Prosthesis (§ 874.3450)  
Official Contact: Alicia E. Farage  
Senior Regulatory Affairs Specialist  
Smith & Nephew, Inc.  
ENT Division  
2925 Appling Road  
Bartlett, TN 38133  
Telephone: (901) 373-0200  
Fax: (901) 373-0242  
Date Prepared: August 17, 2000

The Smith & Nephew Off-Centered PORP is substantially equivalent to the HAPEX TORP and PORP marketed by Smith & Nephew, Inc., ENT Division, the Tuebingen Type Bell marketed by Heinz Kurz GmbH, and the HA/Gold Partial Offset marketed by Mednet Locator. Summarized information follows in tabular form.

### Intended Use

The Smith & Nephew Off-Centered PORP has the same intended use as the HAPEX PORP, Tuebingen Type Bell and the HA/Gold Partial Offset: partial reconstruction of the ossicular chain that has lost its function due to disease, trauma, or congenital defect.

### Head Material

The Smith & Nephew Off-Centered PORP uses hydroxylapatite, the same material as the heads of the HAPEX PORP and the HA/Gold Partial Offset. The head of Tuebingen Type Bell is made from titanium.

### Shaft Material

The Smith & Nephew Off-Centered PORP utilizes titanium, the same material as the Tuebingen Type Bell for the shaft. However, the HA/Gold Partial Offset uses gold for the shaft material. The HAPEX PORP has a shaft of HAPEX.

**Design Features**

The shaft of the Smith & Nephew Off-Centered PORP is not trimmable. This is the same as the shafts of the Tuebingen Type Bell and HA/Gold Partial Offset. Only the HAPEX PORP's shaft is trimmable. The HA head of the Smith & Nephew Off-Centered PORP is an offset oval with a depression into which the shaft fits. The head of the HAPEX PORP is also oval while the offset heads of the Tuebingen Type Bell and HA/Gold Partial Offset are round.

	<b>Smith &amp; Nephew Off-Centered PORP (Smith &amp; Nephew ENT Division)</b>	<b>HAPEX PORP (Smith &amp; Nephew ENT Division)</b>	<b>Tuebingen Type Bell (Heinz Kurz GmbH)</b>	<b>HA/Gold Partial Offset (Mednet Locator)</b>
<b>Intended Use</b>	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain
<b>Head Material</b>	Hydroxylapatite	Hydroxylapatite	Titanium	Hydroxylapatite
<b>Head Shape</b>	Oval	Oval	Round	Round
<b>Shaft Material</b>	Titanium	HAPEX	Titanium	Gold
<b>Intra-operative Sizing</b>	No	Yes	No	No
<b>How Supplied</b>	Sterile	Sterile	Sterile	Sterile

Differences between the Smith & Nephew Off-Centered PORP and the predicate devices should not affect the safety or effectiveness.



AUG 29 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Smith & Nephew, Inc.  
Ms. Alicia Farage  
Sr. Regulatory Affairs Specialist  
2925 Appling Road  
Bartlett, TN 38133

Re: K002464  
Trade Name: Partial Ossicular Replacement Prosthesis  
Regulatory Class: II  
Product Code: 77ETB  
Dated: August 08, 2000  
Received: August 10, 2000

Dear Ms. Farage:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Nancy C. Brogdon".

Nancy C. Brogdon  
Acting Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) Number:

Device Name: Smith & Nephew Off-Centered PORP®

Indications For Use:

- Otosclerosis
- Congenital fixation of the stapes
- When previous remedial surgery has been unsuccessful for the treatment of hearing loss due to otosclerosis, and a significant conductive loss remains with good cochlear reserve.
- Chronic middle ear disease
- Trauma

*JS for Mon*

*Loren Bohm*  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K002464